A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after Final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on February 2, 2010 has been entered.

Claims 5, 59 and 60 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 5, 59 and 60 have not been further treated on the merits.

New claim 61 is presented. Claims 1-5, 44-49 and 52-61 are now pending. However, claims 44-48 remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. Claims 5, 59 and 60 are presently withdrawn from consideration for the reason set forth *supra*. All of the claims that are presently under consideration are drawn to compositions.

The present application is afforded an effective date of September 23, 2003. Provisional application 60/412,958 fails to recite the ranges herein claimed.

The disclosure is objected to for the following informalities:

The status identifier for instant claim 49 is "currently amended." No amendment to the claim is noted.

The status identifier for claim 52, i.e., "(New)," is also incorrect. Claim 52 was newly presented on July 1, 2009.

Appropriate correction is required.

The abstract of the disclosure is objected to because the subject matter under consideration excludes regimens. Correction is required. See MPEP § 608.01(b).

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

There is no recitation in the specification of a pharmaceutical composition comprising a unit dosage form of rifalazil in an amount between 0.1 and 5 mg, wherein the instructions are for daily administration for a period of 4 to 10 days, as recited in claim 58.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 58 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. No support is found in the specification for the recitation "wherein the instructions are for daily administration for a period of 4 to 10 days," as recited in claim 58.

See *In re Rasmussen*, 211USPQ 323 (CCPA 1981).

Applicants' arguments with respect to claims 1-3, 5 and 49-51, that were rejected under 35 U.S.C. 103 as being unpatentable over Rose et al., U.S. Patent 6,316,433, in view of Remington's Pharmaceutical Sciences, in the last Office Action, have been considered but are moot in view of the new grounds of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 49 and 52-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisenstein, B., US 2004/0106590, in view of Remington's Pharmaceutical Sciences.

Eisenstein teaches single dose oral administration of compositions, that may be in the form of tablets or capsules, comprising rifalazil in an amount 0.01 mg to 1000 mg. Oral preparations in the amount of 5 mg are disclosed. See paragraphs 26-30 on page 3. Dosing may be daily, as required by the instructions of instant claims 53-57, such as for 1-14 days or 1 to 31 days. See paragraph 8 on page 1. As required by instant claim 49, an initial dose may be administered and then subsequently followed by a maintenance dose. See paragraph 8 on page 1 and claim 9 on page 6. Remington further provides motivation to prepare a pharmaceutical formulation for oral administration comprising an antibiotic having first and second dosages with a higher

amount of active antibiotic in the first dosage unit, as required by instant claim 49. Loading doses are used in many drug regimens when an urgent need exists to achieve a drug steady state.

All pharmaceutical preparations that are dispensed to a patient are packaged in pharmaceutical containers along with instructions for administration. Eisenstein teaches the inclusion of instructional material on page 2, paragraph 13. The mere placement of instructions within a formulation comprising rifalazil would have been within the general knowledge of one of ordinary skill in the art at the time of the invention. Such a person would have been motivated to do so to promote proper use of the formulation to patients in need thereof and to facilitate patient compliance with a prescribed regimen. Providing such a formulation in a portable container, or in unit dose packaging, that can be transported to allow for convenient dosing, is conventional.

Claims 53-58 are drawn to compositions having instructions for administration. It has been held that Applicants are not entitled to patent a known product by simply attaching a set of instructions to that product. See *In re Ngai*, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004).

The determination of an optimal dosing regimen is well within the purview of those skilled in the art through no more than routine experimentation. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II).

Intended use confers no patentable weight to composition claims. A pharmaceutical composition must be both new and unobvious to one skilled in the art. *In re Hack*, 114 USPQ 161 (CCPA 1957). Claim 49 recites “providing instructions for

the use of said formulation," and the use is as an antibiotic. However, the instant composition claims do not have any structural differences from the prior art compositions. Therefore, there is no patentable distinction between the claimed invention and the prior art compositions. The pharmaceutical compositions that are disclosed by Eisenstein are capable of performing the same antimicrobial use as those instantly claimed.

Remington is properly applied as a secondary reference to show a dosing regimen wherein a higher amount of active antibiotic, i.e., in a loading dose regimen, is dispensed in a first dosage to achieve a therapeutic drug concentration quickly. Such loading doses, as taught by Remington, reflect conventional practice in that the first dose has a higher amount of drug and is followed by a second lower dose, considered to be a maintenance dose.

In view of the combined teachings of Eisenstein and Remington, one skilled in the art of formulation chemistry would have been motivated to prepare unit dose packaging of the drug rifalazil in an amount between 0.1-5 mg/unit for oral administration, optionally with instructions. A unit dosage is a finite, discrete drug entity having a specific amount of that drug. Such packaging is entirely conventional.

According to Remington, packaging of pharmaceutical agents as unit doses, along with instructions thereto, comprising a loading dose, followed by a second, lower dosage unit, is conventional therapeutic practice.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 27, 2010

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614